

Research Process - Frequently Asked Questions (FAQs)

Q: What is the process of developing a research study?

- Develop your questions.
- Think through what you want to know- what information do you need to improve patient care or increase knowledge in the area you are studying?
- What data will you need to collect?
- How will you measure that data?
- Determine what permission you will need to gather your data.
- Contact your employer's or school's Institutional Review Board (IRB)

Q: What preparation do I need to conduct research?

A: All persons conducting research need to take a course on the protection of human subjects and provide proof of successfully completing that course to their Institutional Review Board. The National Institute for Health provides a free course, which can be found at <http://phrp.nihtraining.com/users/login.php>. Your institution may also have access to their preferred course.

Q: What is an Institutional Review Board (IRB)?

A: An IRB is a group that has been formally designated to assure that proper steps are taken to protect the welfare and rights of human subjects in research. In accordance with Food and Drug Enforcement Agency (FDA) regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. In order to protect the rights of humans in research, IRB groups periodically meet to review the protocols and materials researchers submit. Approval of protocols is designed to ensure the welfare of human subjects and to protect their rights as research participants. IRBs are generally in place in hospitals, universities, other healthcare settings, and places of business. If you call your HR department they can direct you to the appropriate committee.

Q: Do I need to be concerned with the Health Insurance Portability and Accountability Act (HIPAA)?

A: Many changes are happening in health care facilities to protect the rights of patients. As part of any research you need to adhere to your agency HIPAA requirements. For some IRBs and sub-populations of participants a confidentiality and privacy agreement may need to be approved. We recommend that you check with your respective organizations.

Q: In terms of IRB approvals, what if I go to school or work in a particular agency, but plan to do my research in one or more additional agencies?

A: A separate IRB approval is generally required from each agency affiliation. For example if you are a student, you will need an IRB approval from your university and from the place where you will collect data. If you are a clinician who plans to collect data from multiple sites, you will need multiple IRB approvals from all the sites where you intend to collect data. This is very important, in order to protect all parties involved. Always check with your employer or school before proceeding with research. If you have additional questions, members of the NYSNA Council of Nursing Research may be able to offer suggestions.

Q: What types of research must be submitted to the IRB?

A: All research involving the collection of data from human subjects must be submitted to the IRB for review. Some research activities are exempt from full IRB review but the IRB must confirm that an exemption is appropriate.

Q: What is the process for submitting to an IRB?

A: Your IRB will guide you through their process. At the very least, you will need to provide an abstract of your study, planned procedures, and supply samples of consent forms and any data collection tools to be used.

Most IRB applications include the following:

- Description of your qualifications to conduct the research
- Statement of goals
- Purpose statement
- Discussion of participants, such as number of people to be in the study, characteristics of the sample, age range, reasons for exclusion or inclusion in the study.
- Sources and copies of research materials, for example will you do interviews, collect bodily fluids, measurements?
- Plans for your recruitment into the study, procedures, and consent, this would include copies of your consent form and all of the items you will use in the study
- Description of potential risks to participants and plans to protect from such risks

Q: What does the IRB do with all of this information?

- Once all your materials are in, the IRB will review them. There are four types of reviews, namely, exempt, expedited or full reviews, based on the perceived risks to the participants. Your IRB will determine which category under which your study should be reviewed.
- You can expect a review to take anywhere from 2 weeks to 8 weeks, depending on the timeframe of submission and the degree of review required.

Q: Does NYSNA require that the study be ready for IRB review prior to asking for help from the research council?

- Each request will be examined on an individual basis. NYSNA welcomes inquiries at all stages of the research process.
- Requests about the research process itself or about issues a nurse is experiencing early in the research process are examples of work where we might be helpful prior to the IRB process.
- If you are a student, NYSNA will need to know if you have taken a research course and will request the name of your professor overseeing your research project.